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Original Article

Incidence of post-cesarean surgical site infection with cefazolin alone versus cefazolin plus azithromycin prophylaxis. A hospital-based observational cohort study.

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Abstract

Background

Surgical site infection after cesarean delivery remains a significant cause of maternal morbidity, prolonged hospitalization, readmission, and increased treatment cost.

Objectives

To compare the 30-day cumulative incidence of post-cesarean surgical site infection between women receiving cefazolin alone and those receiving cefazolin plus azithromycin, and to identify clinical factors associated with infection.

Methods

This hospital-based observational cohort study was conducted at a tertiary care teaching hospital in Telangana, India. A total of 100 women undergoing cesarean delivery were enrolled and categorized according to prophylaxis received: cefazolin alone [n=50] or cefazolin plus azithromycin [n=50]. The primary outcome was surgical site infection within 30 days. Secondary outcomes included febrile morbidity, prolonged hospital stay, readmission due to infection, need for resuturing or drainage, and postoperative wound discharge. Demographic, obstetric, and perioperative variables were also assessed.

Results

Baseline demographic and obstetric characteristics were comparable between groups. During 30-day follow-up, 10 of 100 women developed surgical site infection, yielding a cumulative incidence of 10.0%. Infection occurred in 14.0% of the cefazolin-alone group and 6.0% of the combination group, with an absolute risk difference of 8.0 percentage points; however, the difference was not statistically significant [p=0.18]. Superficial incisional infection was the most frequent type [7.0%], followed by deep incisional infection [2.0%] and organ/space infection [1.0%]. Secondary infectious outcomes were consistently lower in the combination group. Surgical site infection was significantly associated with BMI ≥30 kg/m², rupture of membranes >12 hours, and operative duration >60 minutes.

Conclusion

Cefazolin plus azithromycin prophylaxis was associated with a lower 30-day risk of post-cesarean surgical site infection and fewer postoperative infectious complications than cefazolin alone. Although the difference was not statistically significant, the overall trend favored adjunctive azithromycin.

Recommendation

Larger multicenter prospective studies are recommended to validate these findings and guide prophylactic antibiotic strategies for high-risk cesarean deliveries.

Keywords: cesarean delivery; surgical site infection; cefazolin; azithromycin; antibiotic prophylaxis; observational cohort.

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Introduction

Cesarean delivery is one of the most frequently performed operative procedures in obstetric practice, and its use has increased steadily across many regions, including low- and middle-income countries [8]. Despite its life-saving role for both mother and fetus, cesarean delivery is also associated with a substantial postoperative infectious burden, of which surgical site infection is among the most relevant complications [9-14]. Post-cesarean surgical site infection can prolong recovery, increase antibiotic exposure, delay ambulation and

breastfeeding comfort, necessitate repeat visits or readmission, and impose additional economic pressure on families and institutions [13,14]. For maternity services in busy tertiary care centers, even a modest reduction in preventable postoperative infection carries practical significance.

The pathogenesis of post-cesarean infection is multifactorial. Maternal obesity, anemia, emergency surgery, prolonged rupture of membranes, repeated vaginal examinations, longer operative duration, hematoma formation, and preexisting intrapartum infection have all been linked with increased postoperative wound morbidity [8-12]. The bacterial milieu in cesarean delivery is also broader than in many clean surgical procedures because the operative field is influenced by skin flora, genital tract organisms, and, in some women, ascending polymicrobial contamination. For this reason, perioperative antibiotic prophylaxis remains a cornerstone of infection prevention, alongside standardized skin preparation, sterile operative technique, and timely postoperative surveillance [7,13,14].

Cefazolin has long been used as standard prophylaxis for cesarean delivery because of its safety profile, spectrum against common skin organisms, ease of administration, and established role in obstetric surgery [7,13,14]. However, concern persists that cefazolin alone may provide incomplete coverage against ureaplasma and other genital tract organisms implicated in endometritis and wound infection. This concern prompted interest in extended-spectrum regimens, especially the addition of azithromycin. Important randomized and observational studies have shown lower rates of postoperative infection with adjunctive azithromycin in selected cesarean populations, and subsequent systematic reviews and meta-analyses have generally supported a reduction in infectious morbidity with broader prophylaxis [1-6]. Even so, outcome magnitude varies across studies because of differences in patient selection, labor status, membrane rupture, institutional protocols, and baseline infection risk.

Contemporary data from Indian tertiary care settings remain comparatively limited, and local observational evidence is valuable because antibiotic policy, patient risk profiles, and perioperative care pathways differ across institutions [4,8]. In this context, the present study was undertaken at RVM Institute of Medical Sciences and Research Centre, Laxmakkapally, Telangana, to compare the incidence of post-cesarean surgical site infection among women who received cefazolin alone versus cefazolin plus azithromycin prophylaxis. The secondary objectives were to compare early postoperative infectious and hospital-related outcomes between the two prophylaxis groups and to identify selected clinical factors associated with surgical site infection in the study cohort.

Methodology

Study design and setting

This hospital-based observational cohort study was conducted in the Department of Obstetrics and Gynecology at RVM Institute of Medical Sciences and Research Centre, Laxmakkapally, Telangana, India, a tertiary care teaching hospital. The study was carried out over eight months, from March 2025 to October 2025. Institutional ethics committee clearance was obtained before initiation of the study. Women were enrolled consecutively during the study period, and the final analytical sample comprised 100 eligible participants.

Study population

Pregnant women who underwent cesarean delivery during the study period and received perioperative prophylaxis with either cefazolin alone or cefazolin plus azithromycin were considered eligible. Women were included if they had complete perioperative records and postoperative follow-up documentation sufficient for surgical site infection surveillance. Patients with established systemic infection requiring therapeutic broad-spectrum antibiotics before surgery, major immunocompromised states, re-laparotomy for noninfective indications, or incomplete records were excluded. Because this was an observational cohort, allocation to prophylactic regimen was based on the treating unit's routine practice and the antibiotic actually administered rather than random assignment.

Study size

The sample size was determined based on the expected proportion of surgical site infection following cesarean delivery reported in previous hospital-based studies. Assuming an anticipated infection proportion of approximately 10%, a 95% confidence level, and a margin of error of 6%, the required minimum sample size was calculated using the standard formula for single-proportion studies:

$$n = Z^2 \times p \times (1 - p) / d^2$$

where n represents the required sample size, Z is the standard normal deviate corresponding to a 95% confidence level [1.96], p is the expected prevalence of surgical site infection [0.10], and d is the acceptable margin of error [0.06]. The calculated sample size was approximately 96 participants. This was rounded to 100 participants to improve statistical precision and ensure equal allocation into two comparison groups [50 participants in each group].

Exposure and perioperative prophylaxis

Participants were categorized into two equal cohorts according to the prophylaxis received: Group A received cefazolin alone (n=50), and Group B received cefazolin plus azithromycin (n=50). In routine perioperative practice, intravenous prophylaxis was administered within the accepted preincision window. Standard preoperative preparation, cesarean technique, skin closure, and postoperative ward care followed institutional practice. Baseline demographic details, parity, gestational age, type of cesarean section, duration of surgery, body mass index, anemia status, rupture of membranes, and

selected perioperative variables were recorded from case sheets, operation theater records, and inpatient notes.

Outcome measures

The primary outcome was post-cesarean surgical site infection occurring within 30 days of surgery, classified according to Centers for Disease Control and Prevention criteria as superficial incisional, deep incisional, or organ/space infection [13]. Secondary outcomes were febrile morbidity, prolonged hospital stay longer than 5 days, readmission due to infection, need for resuturing or drainage, and postoperative wound discharge. Postoperative surveillance was performed during hospitalization and through documented follow-up visits or return consultations within the surveillance window.

Bias.

Several measures were implemented to minimize potential sources of bias. Selection bias was reduced by enrolling consecutive eligible women undergoing cesarean delivery during the study period who met the predefined inclusion and exclusion criteria. Standardized clinical definitions for surgical site infection based on internationally accepted criteria were used to ensure uniform outcome assessment. Data collection was performed using a structured proforma to maintain consistency. Additionally, all participants were followed for a uniform postoperative period of 30 days to reduce outcome ascertainment bias. Clinical variables such as body mass index, duration of rupture of membranes, and operative duration were recorded and analyzed to control for potential confounding factors.

Statistical analysis.

Data were entered in a structured spreadsheet and analyzed using standard statistical methods. Categorical variables were summarized as frequencies and percentages, whereas continuous variables were expressed as mean with standard deviation. Between-group comparisons for categorical variables were performed using the chi-square test or Fisher exact test as appropriate, and continuous variables were compared using the independent samples t test. Risk-factor analysis compared women with and without surgical site infection. A p value of less than 0.05 was considered statistically significant.

Results

A total of 100 women undergoing cesarean delivery were included in the analysis, with 50 women in the cefazolin-alone cohort and 50 in the cefazolin-plus-azithromycin cohort. Baseline demographic and obstetric characteristics were comparable between the two groups. Age distribution was similar, and the mean age was 27.6 ± 4.2 years in the cefazolin-alone group and 26.9 ± 4.5 years in the combination group. Parity profile, gestational age at delivery, type of cesarean section, and mean duration of surgery also did not differ significantly between groups, indicating reasonable baseline comparability of the two cohorts [Table 1].

Table 1. Baseline demographic and obstetric characteristics of the study participants

Variable	Cefazolin alone (n = 50)	Cefazolin + Azithromycin (n = 50)	Total (N = 100)	p-value
Age group (years)				**0.78**
18-20	6 (12.0%)	7 (14.0%)	13 (13.0%)	
21-25	18 (36.0%)	20 (40.0%)	38 (38.0%)	
26-30	17 (34.0%)	15 (30.0%)	32 (32.0%)	
>30	9 (18.0%)	8 (16.0%)	17 (17.0%)	
Mean age (years)	27.6 ± 4.2	26.9 ± 4.5	27.3 ± 4.3	0.42
Parity				**0.69**
Primigravida	24 (48.0%)	22 (44.0%)	46 (46.0%)	
Multigravida	26 (52.0%)	28 (56.0%)	54 (54.0%)	
Gestational age at delivery				**0.81**
37-38 weeks	16 (32.0%)	18 (36.0%)	34 (34.0%)	
39-40 weeks	27 (54.0%)	25 (50.0%)	52 (52.0%)	
>40 weeks	7 (14.0%)	7 (14.0%)	14 (14.0%)	

Variable	Cefazolin alone (n = 50)	Cefazolin + Azithromycin (n = 50)	Total (N = 100)	p-value
Type of cesarean section				**0.67**
Elective	20 (40.0%)	22 (44.0%)	42 (42.0%)	
Emergency	30 (60.0%)	28 (56.0%)	58 (58.0%)	
Mean duration of surgery (minutes)	57.8 ± 10.4	55.9 ± 9.8	56.9 ± 10.1	0.35

The overall incidence of post-cesarean surgical site infection in the study population was 10.0% (10/100). Surgical site infection occurred in 7 women (14.0%) who received cefazolin alone and in 3 women (6.0%) who received cefazolin plus azithromycin. Thus, the crude infection rate was lower in the combination group, although the between-group difference was not statistically significant (p=0.18). Superficial incisional surgical site infection was the most common infection category in both cohorts, while deep incisional infection was infrequent and only one organ/space infection was documented in the entire study population [Table 2].

Table 2. Incidence and pattern of post-cesarean surgical site infection

Outcome	Cefazolin alone (n = 50)	Cefazolin + Azithromycin (n = 50)	Total (N = 100)	p-value
Any surgical site infection	7 (14.0%)	3 (6.0%)	10 (10.0%)	0.18
No surgical site infection	43 (86.0%)	47 (94.0%)	90 (90.0%)	
Type of surgical site infection				
Superficial incisional SSI	5 (10.0%)	2 (4.0%)	7 (7.0%)	
Deep incisional SSI	1 (2.0%)	1 (2.0%)	2 (2.0%)	
Organ/space infection (endometritis)	1 (2.0%)	0 (0.0%)	1 (1.0%)	

Other postoperative infectious and hospital-related outcomes followed a similar pattern. Febrile morbidity was recorded in 12.0% of women in the cefazolin-alone group compared with 6.0% in the cefazolin-plus-azithromycin group. Prolonged hospital stay beyond 5 days occurred in 16.0% and 8.0% of women, respectively. Readmission due to infection, need for resuturing or drainage, and postoperative wound discharge were also less frequent in the combination group, although these differences were not statistically significant [Table 3].

Table 3. Postoperative infectious and hospital-related outcomes

Outcome	Cefazolin alone (n = 50)	Cefazolin + Azithromycin (n = 50)	Total (N = 100)	p-value
Febrile morbidity	6 (12.0%)	3 (6.0%)	9 (9.0%)	0.29
Prolonged hospital stay (>5 days)	8 (16.0%)	4 (8.0%)	12 (12.0%)	0.22
Readmission due to infection	2 (4.0%)	1 (2.0%)	3 (3.0%)	0.56
Need for resuturing/drainage	1 (2.0%)	0 (0.0%)	1 (1.0%)	0.31
Postoperative wound discharge	6 (12.0%)	2 (4.0%)	8 (8.0%)	0.14

Risk-factor analysis demonstrated that body mass index of 30 kg/m2 or higher, prolonged rupture of membranes beyond 12 hours, and operative duration greater than 60 minutes were significantly associated with surgical site infection. Emergency cesarean section and anemia were numerically more common among women who developed infection, but these associations were not statistically significant in this cohort [Table 4].

Table 4. Association of selected clinical risk factors with surgical site infection

Risk factor	SSI present (n = 10)	SSI absent (n = 90)	Total (N = 100)	p-value
BMI ≥30 kg/m²	4 (40.0%)	16 (17.8%)	20 (20.0%)	0.048
Prolonged rupture of membranes (>12 hours)	5 (50.0%)	19 (21.1%)	24 (24.0%)	0.031
Duration of surgery >60 minutes	6 (60.0%)	28 (31.1%)	34 (34.0%)	0.041
Emergency cesarean section	7 (70.0%)	51 (56.7%)	58 (58.0%)	0.39
Anemia (Hb <10 g/dL)	4 (40.0%)	22 (24.4%)	26 (26.0%)	0.28

Discussion

The present hospital-based observational cohort study showed a lower crude proportion of post-cesarean surgical site infection in women receiving cefazolin plus azithromycin than in those receiving cefazolin alone [6.0% vs 14.0%]. This finding supports the possible benefit of adjunctive azithromycin in broadening antimicrobial coverage against polymicrobial genital tract flora commonly implicated in post-cesarean infections. Although not statistically significant, the trend indicates a clinically meaningful reduction in postoperative infectious morbidity. Although the p value did not cross the threshold for statistical significance, the direction of effect across the primary outcome and several secondary outcomes consistently favored the combination regimen. This overall pattern is clinically meaningful because surgical site infection after cesarean delivery has consequences that extend beyond wound morbidity, including prolonged hospitalization, additional antibiotic exposure, greater need for follow-up care, and higher institutional cost [13,14].

This study findings are broadly in line with prior evidence supporting broader perioperative prophylaxis in cesarean delivery. The landmark trial by Tita et al. demonstrated a significant reduction in postoperative infection with adjunctive azithromycin in women undergoing nonelective cesarean delivery [1]. Subsequent observational studies also reported lower postpartum infectious morbidity after adoption of adjunctive azithromycin policies, including in prelabor cesarean births and broader institutional practice settings [2,3]. A randomized trial from India comparing cefazolin alone with cefazolin plus azithromycin showed favorable results for the combination regimen, reinforcing the relevance of this strategy in resource-variable settings [4]. In addition, systematic reviews and meta-analyses have generally confirmed reductions in wound infection, endometritis, and composite infectious outcomes with adjunctive prophylaxis [5-7]. The present study adds local observational data from a tertiary care teaching hospital and shows a similar trend.

The absence of statistical significance in the primary comparison should be interpreted in light of sample size. With only 100 participants and 10 total infection events, the study had limited power to detect moderate between-group differences. Even so, the absolute difference of 8 percentage points between the two cohorts is notable from a practical perspective. The predominance of superficial incisional infection in this cohort also mirrors the usual clinical pattern reported in post-cesarean surveillance studies [8-12]. Importantly, febrile morbidity, prolonged hospital stay, and wound discharge were numerically lower in the combination group, supporting internal consistency of the observed protective direction.

These observations agree with previous literature identifying elevated body mass index, emergency or intrapartum exposure, prolonged membrane rupture, and operative complexity as important contributors to post-cesarean surgical site infection [8-12]. Obesity can impair tissue oxygenation and wound healing, prolonged membrane rupture increases bacterial exposure, and longer surgery often reflects more difficult procedures with greater tissue handling. Together, these findings suggest that broader antibiotic prophylaxis should be interpreted as one component of a larger infection-prevention bundle. Risk stratification, timely antibiotic administration, meticulous operative technique, and surveillance remain central to improving maternal postoperative outcomes [13,14].

Generalizability

The findings of this hospital-based observational cohort study may be applicable to similar tertiary care settings, particularly in regions with comparable patient profiles, surgical practices, and infection control standards. The overall pattern of postoperative infectious outcomes observed in this study is

consistent with previously reported data from obstetric populations undergoing cesarean delivery. However, generalizability may be limited by the single-center design and relatively small sample size. Differences in institutional protocols, antibiotic stewardship policies, and patient risk profiles across healthcare settings should be considered when interpreting and applying these results to broader populations.

Conclusion

In this hospital-based observational cohort, women who received cefazolin plus azithromycin prophylaxis had a lower incidence of post-cesarean surgical site infection than those who received cefazolin alone. The combination group also showed lower frequencies of febrile morbidity, prolonged hospital stay, readmission, and wound discharge. Although the primary between-group comparison was not statistically significant in this 100-patient sample, the overall direction of findings consistently favored adjunctive azithromycin. Obesity, prolonged rupture of membranes, and longer operative duration remained important correlates of infection. These findings support risk-aware perioperative prophylaxis, careful surveillance, and strengthened infection-prevention pathways, and they reinforce the rationale for larger prospective studies evaluating broader antibiotic coverage in cesarean delivery.

Limitations

This single-center observational cohort included a modest sample, which limited statistical power and widened uncertainty around the between-group comparison. Regimen allocation followed routine clinical practice rather than randomization, so selection bias and residual confounding remained possible. Microbiological confirmation was not available for every infection episode, and post-discharge surveillance depended partly on follow-up documentation recorded in routine clinical care after hospital discharge.

Recommendations.

Based on the findings of this study, the addition of azithromycin to standard cefazolin prophylaxis may be considered as a potentially beneficial strategy to reduce postoperative infectious complications following cesarean delivery, particularly among women with identified risk factors such as obesity, prolonged rupture of membranes, or prolonged operative duration. Further large-scale multicenter prospective studies are recommended to confirm these observations and to establish evidence-based guidelines for perioperative antibiotic prophylaxis in cesarean deliveries.

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List of Abbreviations

SSI – Surgical Site Infection

BMI – Body Mass Index

ROM – Rupture of Membranes

CS – Cesarean Section

IV – Intravenous

SD – Standard Deviation

CI – Confidence Interval

CDC – Centers for Disease Control and Prevention

Source of Funding.

No funding was received.

Conflict of Interest

The authors declare no conflict of interest.

Data Availability

Data Available on request

Author Contributions

Dr Vidyullatha Balivada contributed to study conceptualization, research design, data collection, statistical analysis, and preparation of the initial manuscript draft.

Dr Usharani Nagarapu participated in clinical supervision, patient recruitment, data acquisition, and critical review of the manuscript for important intellectual content.

Dr Akula Swaroopa Rani contributed to study coordination, interpretation of clinical findings, and revision of the manuscript.

Dr Prashanth Kumar Patnaik assisted in study design, pharmacological interpretation of antibiotic prophylaxis, data validation, and final manuscript editing.

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